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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,347	01/11/2002	M. Judah Folkman	05213-0880 (43170-249874)	7487
23370	7590	09/27/2004	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			HUFF, SHEELA JITENDRA	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,347

Applicant(s)

FOLKMAN ET AL.

Examiner

Sheela J Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) 23-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>sequence alignments</u> . |

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DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 21-22 in the reply filed on 8/27/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 23-40 are withdrawn from consideration.

Information Disclosure Statement

The IDS filed 8/13/02 has an incorrect citation. Reference 1 is incorrect.

The remaining reference on the Ids filed 8/13/02 and the reference filed 1/11/02 have been considered and an initialed copy of the PTO-1449 is enclosed.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The dates of 09/154302 and 60/026263 are incorrect.

Priority

Applicant is requested to update that status of 09/154302 in the first line of the specification.

Claim Rejections - 35 USC 112

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Claims 21-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification does not contain a written description of the invention in such full, clear, concise, and exact terms or in sufficient detail that one skilled in the art can reasonably conclude that applicant had possession of the claimed invention at the time of filing.

The claims are drawn to SEQ ID No. 4.

The specification discloses that endostatin refers to a protein that is about 18-20 kDa in size and discloses SEQ ID No. 4, however the instant claims are drawn to any anti-angiogenic inhibitory peptide fragment of endostatin protein. The specification further discloses precursor forms, but does not provide any guidance regarding such forms, including definitive characteristics or precursors forms and size of precursor forms such that one of skill in the art would predictably be enabled to identify a precursor form. It is further not clear if the precursor forms even possess anti-angiogenic activity. The specification also contemplates modified proteins and peptides having substantially similar amino acid sequence to the 18-20 endostatin, which are able to inhibit proliferation of endothelial cells in vitro. Thus, the term "endostatin" encompasses a wide variety of different proteins and applicant has only disclosed one species. The instant disclosure of a single species does not adequately describe the scope of the claimed genus, which encompasses a substantial variety of subgenera. A

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description of a genus may be achieved by means of a recitation of a representative species falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features of the claimed genus. There is no description of the conserved regions which are critical to the structure and function of the genus claimed. The specification proposes to discover other members of the genus by modifying the 18-20 kDa polypeptide or by isolating other similar polypeptides from other sources. There is no description, however, of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Structural features that could distinguish the compounds in the genus from others excluded are missing from the disclosure. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify the polypeptides encompassed and no identifying characteristic or property of the instant polypeptides is provided such that one of skill would be able to predictably identify the encompassed molecules as being identical to those instantly claimed.

Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, the disclosure of specific nucleotide sequences and the ability to screen, is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure

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fails to provide a representative number of species to describe and enable the genus as broadly claimed.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.

The terminology "substantially homologous sequence to" is new matter. The specification does not contemplate sequence homologous to SEQ ID NO. 4.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 21 and 22 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 18 of U.S. Patent No. 6746865. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant set of claims is directed to an isolated nucleic acid molecule **comprising** a nucleotide sequence encoding an endostatin and this sequence encompasses more than the sequence of the patent which is directed to a nucleic acid sequence that codes for a protein with an NC 1 fragment (ie endostatin).

Claims 21 and 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-39 of copending Application No. 10/232316. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant set of claims is directed to an isolated nucleic acid molecule **comprising** a nucleotide sequence encoding an endostatin and this sequence encompasses more than the sequence of the patent which is directed to a nucleic acid sequence that codes for a protein with an NC 1 fragment (ie endostatin).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21 and 22 are rejected under 35 U.S.C. 102(e) as being anticipated by Violand et al US 6653098 (priority to 2/23/98).

This reference discloses and claims SEQ ID NO. 9 which has 100% similarity with SEQ ID No 4 of the instant invention (see sequence alignment-enclosed).

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al US 5643783.

This reference discloses and claims SEQ ID NO. 4 which has 100% similarity with SEQ ID No 4 of the instant invention (see sequence alignment-enclosed).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. MacDonald et al US 6201104 discloses SEQ ID No. 30 which


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has 100% similarity with SEQ ID No 4 of the instant invention (see sequence alignment-enclosed).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Mondays and Thursdays from 5:30am to 2:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Sheela J Huff
Primary Examiner
Art Unit 1642

sjh

RESULT 4
US-08-159-784-4
; Sequence 4, Application US/08159784
; Patent No. 5643783
; GENERAL INFORMATION:
; APPLICANT: Bjorn R. Olsen
; TITLE OF INVENTION: NOVEL COLLAGEN AND USES THEREOF
; NUMBER OF SEQUENCES: 9
; CORRESPONDENCE ADDRESS:
; ADDRESSEE: Fish & Richardson
; STREET: 225 Franklin Street
; CITY: Boston
; STATE: Massachusetts
; COUNTRY: U.S.A.
; ZIP: 02110-2804
; COMPUTER READABLE FORM:
; MEDIUM TYPE: 3.5" Diskette, 1.44 Mb
; COMPUTER: IBM PS/2 Model 50Z or 55SX
; OPERATING SYSTEM: MS-DOS (Version 5.0)
; SOFTWARE: WordPerfect (Version 5.1)
; CURRENT APPLICATION DATA:
; APPLICATION NUMBER: US/08/159,784
; FILING DATE: December 1, 1993
; CLASSIFICATION: 530
; PRIOR APPLICATION DATA:
; APPLICATION NUMBER:
; FILING DATE:
; ATTORNEY/AGENT INFORMATION:
; NAME: John F. Freeman
; REGISTRATION NUMBER: 29,066
; REFERENCE/DOCKET NUMBER: 00246/170001
; TELECOMMUNICATION INFORMATION:
; TELEPHONE: (617) 542-5070
; TELEFAX: (617) 542-8906
; TELEX: 200154
; INFORMATION FOR SEQ ID NO: 4:
; SEQUENCE CHARACTERISTICS:
; LENGTH: 3394
; TYPE: nucleic acid
; STRANDEDNESS: single
; TOPOLOGY: linear
US-08-159-784-4

Query Match
Best Local Similarity 100.0%; Score 546; DB 1; Length 3394;
Matches 546; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
QY 1 CACAGCCAGCGGACCTCCAGCCGGTGTCCACCTGGTGGCGTCAACAGCCCCCTGTCA 60
DB 1504 CACAGCCAGCGGACCTCCAGCCGGTGTCCACCTGGTGGCGTCAACAGCCCCCTGTCA 1563
QY 61 GGCGGATCGGGGACATCCGCGGGCGGACTTCCAGTGTCTCCAGCAGCGCGGCCGTTG 120
DB 1564 GGCGGATCGGGGACATCCGCGGGCGGACTTCCAGTGTCTCCAGCAGCGCGGCCGTTG 1623
QY 121 GGCGTGGGGGACATCCGCGGGCGGACTTCCAGTGTCTCCAGCAGCGCGGCCGTTG 180
DB 1624 GGCGTGGGGGACATCCGCGGGCGGACTTCCAGTGTCTCCAGCAGCGCGGCCGTTG 1683
QY 181 GTGCGCGGTGGGACATCCGCGGGCGGACTTCCAGTGTCTCCAGCAGCGCGGCCGTTG 240
DB 1684 GTGCGCGGTGGGACATCCGCGGGCGGACTTCCAGTGTCTCCAGCAGCGCGGCCGTTG 1743
QY 241 CCAGCTGGGAGGCTCTGTCTCAGGCTCTGAGGGTCCGCTCAAGCCCGGGGACGCGATC 300
DB 1744 CCAGCTGGGAGGCTCTGTCTCAGGCTCTGAGGGTCCGCTCAAGCCCGGGGACGCGATC 1803
QY 301 TTCTCTTTTTCAGGCGAAGGACGTCTGTAGGCGCCCCACCTGGCCCCAGAGCGTGTGG 360
DB 1804 TTCTCTTTTTCAGGCGAAGGACGTCTGTAGGCGCCCCACCTGGCCCCAGAGCGTGTGG 1863
QY 361 CATGGCTCGGACCCCAACCGGCGGAGCTGACCGAGAGTACTGTGAGACGTGGCGGACG 420

Db 1864 CATGGCTCGGACCCCAACCGGCGGAGGCTGACCGAGAGCTACTGTGAGACGTGGCGGAGG 1923
QY 421 GAGGCTCCCTCGGCGACCGGCGGAGGCTCTCGCTGTGGGGGGGAGGCTCTCTGGGGCAG 480
Db 1924 GAGGCTCCCTCGGCGACCGGCGGAGGCTCTCGCTGTGGGGGGGAGGCTCTCTGGGGCAG 1983
QY 481 AGTGGCGGAGCTGCCATCAGCCCTACATCGTGCTCTGATTGAGAAAGAGCTTCATGACT 540
Db 1984 AGTGGCGGAGCTGCCATCAGCCCTACATCGTGCTCTGATTGAGAAAGAGCTTCATGACT 2043
QY 541 GCCTCC 546
Db 2044 GCCTCC 2049

RESULT 5
US-09-315-689-6
; Sequence 6, Application US/09315689
; Patent No. 6346510
; GENERAL INFORMATION:
; APPLICANT: Folkman, Judah
; APPLICANT: O'Reilly, Michael
; TITLE OF INVENTION: Therapeutic Antiangiogenic Endostatin Compositions
; FILE REFERENCE: 05213-0229
; CURRENT APPLICATION NUMBER: US/09/315,689
; CURRENT FILING DATE: 1999-05-20
; NUMBER OF SEQ ID NOS: 6
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 6
; LENGTH: 534
; TYPE: DNA
; ORGANISM: Homo sapiens
US-09-315-689-6
Query Match
Best Local Similarity 100.0%; Score 534; DB 4; Length 534;
Matches 534; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
QY 13 GACTTCAGCGCGGCTCCACCTGGTTCGCTCAACGCCCCCTGTGAGGCGGATCGGG 72
DB 1 GACTTCAGCGCGGCTCCACCTGGTTCGCTCAACGCCCCCTGTGAGGCGGATCGGG 60
QY 73 GGCATCCGCGGGCGGACATCCAGTGTCTGAGCAGCGCGGCGGCGGCTGGCGGGC 132
DB 61 GGCATCCGCGGGCGGACATCCAGTGTCTGAGCAGCGCGGCGGCGGCTGGCGGGC 120
QY 133 ACCTTCGCGGCTTCCTGTCTCTCGGCTGCAGGACCTGTACAGCATCTGTGCGCCGTC 192
DB 121 ACCTTCGCGGCTTCCTGTCTCTCGGCTGCAGGACCTGTACAGCATCTGTGCGCCGTC 180
QY 193 GACCGCGAGCGGTGCCATCGTCAACCTGAGGACGAGCTGTGTTCACAGCTGGAG 252
DB 181 GACCGCGAGCGGTGCCATCGTCAACCTGAGGACGAGCTGTGTTCACAGCTGGAG 240
QY 253 GCTCTGTCTCAGGCTCTGAGGGTCCGCTGAAGCCGCGGCGGACGATCTTCTCTTTGAC 312
DB 241 GCTCTGTCTCAGGCTCTGAGGGTCCGCTGAAGCCGCGGCGGACGATCTTCTCTTTGAC 300
QY 313 GGCAGGACGCTCTGAGGACCCCACTGTCGCCCCAGAGACGCTGTGGCATGGCTCGGAC 372
DB 301 GGCAGGACGCTCTGAGGACCCCACTGTCGCCCCAGAGACGCTGTGGCATGGCTCGGAC 360
QY 373 CCGAACCGGCGGAGGCTGACCGGAGCTACTGTGACACGCTGGCGACCGAGGCTCCCTCG 432
DB 361 CCGAACCGGCGGAGGCTGACCGGAGCTACTGTGACACGCTGGCGACCGAGGCTCCCTCG 420
QY 433 GCCACGGCGCAGGCTCTCTCGCTGTGGGGGGGAGGCTCTTGGGGGAGAGTGGCGGAGC 492
DB 421 GCCACGGCGCAGGCTCTCTCGCTGTGGGGGGGAGGCTCTTGGGGGAGAGTGGCGGAGC 480
QY 493 TGCCATCAGCCCTACATCTGTGCTCTGATTGAGAAAGAGCTTCATGACTGCTCC 546
DB 481 TGCCATCAGCCCTACATCTGTGCTCTGATTGAGAAAGAGCTTCATGACTGCTCC 534